

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF SOUTH CAROLINA
ROCK HILL DIVISION

UNITED STATES OF AMERICA)	Criminal No.:
)	
v.)	
)	<u>PLEA AGREEMENT</u>
LEINER HEALTH PRODUCTS, LLC)	

General Provisions

This PLEA AGREEMENT is made this 11th day of June, 2008, between the United States of America, as represented by United States Attorney W. WALTER WILKINS, Assistant United States Attorney WINSTON D. HOLLIDAY, JR., the Defendant, **LEINER HEALTH PRODUCTS, LLC** (hereinafter "**LEINER**"), and Defendants' Attorneys, J. PRESTON STROM, JR., Esquire, and STEPHEN P. ANTHONY, Esquire. IN CONSIDERATION of the mutual promises made herein, the parties hereto agree as follows:

1. The Defendant, **LEINER**, agrees to waive Indictment and arraignment, and plead guilty to a one-count Information, charging MAIL FRAUD, in violation of Title 18, United States Code, § 1341.

In order to sustain its burden of proof as to this offense, the Government is required to prove the following:

On or about December 13, 2006, in the District of South Carolina, the Defendant

- (A) Knowingly devised or knowingly participated in a scheme or artifice to defraud or to obtain money or property by means of false or fraudulent pretenses, representations, or promises as detailed in the Information; and
- (B) In advancing, or furthering, or carrying out this scheme to defraud or to

obtain property by means of false or fraudulent pretenses, representations, or promises, the defendant used the mails, or a private or commercial interstate carrier, or caused them to be used; and

(C) The defendant acted with intent to defraud.

Possible Penalties for 18 U.S.C. § 1341

\$500,000 fine, or twice the gross gain or loss

\$400 special assessment

2. The Defendant agrees to provide detailed financial information to the United States Probation Office prior to sentencing. The Defendant further understands and agrees that any monetary penalty imposed is not dischargeable in bankruptcy.

(A) Fines: The Defendant understands and agrees that the Court may impose a fine pursuant to 18 U.S.C. §§ 3571 and 3572, which fine may be due and payable immediately after sentencing regardless of whether the Defendant has the money to pay the fine. In the event the Defendant does not have the money, the Defendant understands and agrees that the Court may establish a payment schedule, taking into account the Defendant's present and future means of earning money, or of obtaining money to pay the fine.

(B) Restitution: The Defendant agrees to make full restitution under 18 U.S.C. § 3556 in an amount to be determined by the Court at the time of sentencing, which amount is not limited to the count(s) to which the Defendant pled guilty, but will include restitution to each and every identifiable victim who may have been harmed by its scheme or pattern of

criminal activity, pursuant to 18 U.S.C. § 3663. The Defendant agrees to cooperate fully with the government in identifying all victims. The Defendant understands and agrees that full payment of restitution is due immediately after sentencing unless the Court provides, in the interest of justice, for payment on a date certain or in installments over the shortest time in which full payment can be reasonably made. The Defendant further understands and agrees that the government will seek enforcement of any order of restitution, and reserves the right to petition the Court at a later date to increase the amount of any installment payments toward restitution in the interest of justice. Recognizing the Court's statutory obligation to provide restitution to the victims of the Defendant's conduct, the parties agree that fashioning an order of restitution in this case would unduly prolong and complicate the sentencing process, as noted 18 U.S.C. § 3663(a)(1)(B)(ii). This is largely due to the difficulty of identifying and verifying a definable list of victims; that is, those who can demonstrate they purchased over-the-counter drugs manufactured by the Defendant that fall within the problem batches covered by this Agreement. As such, the parties agree that forfeiture is a more appropriate remedy in this instance than restitution.

- (C) Special Assessment: Pursuant to 18 U.S.C. § 3013, the Defendant must pay a special assessment of \$400 for each felony count for which it is

convicted. This special assessment must be paid at or before the time of the guilty plea hearing.

3. The Defendant understands that the matter of sentencing is within the sole discretion of the Court and that the sentence applicable to Defendant's case will be imposed after the Court considers as advisory the United States Sentencing Commission Guidelines, Application Notes and Policy Statements, as well as the factors set forth in Title 18, United States Code, Section 3553(a). The Defendant also understands that Defendant's sentence has not yet been determined by the Court, and that any estimate of a probable sentencing range Defendant may have received from Defendant's attorneys, the Government, or the United States Probation Office is only a prediction, not a promise, and is not binding on the Government, the Probation Office or the Court. The Defendant further understands that the Government retains the right to inform the Court of any relevant facts, to address the Court with respect to the nature of the offense, to respond to questions raised by the Court, to correct any inaccuracies or inadequacies in the presentence report, to respond to any statements made to the Court by or on behalf of the Defendant, and to summarize all evidence which would have been presented at trial to establish a factual basis for the plea.

4. The Defendant agrees that all facts that determine its offense level under the Guidelines and pursuant to any mandatory minimum (including facts that support any specific offense characteristic or other enhancement or adjustment) can be found by the Court at sentencing by a preponderance of the evidence standard and the Court may

consider any reliable evidence, including hearsay. By executing this Agreement, the Defendant understands that it waives any argument that facts that determine its offense level under the Guidelines and pursuant to any mandatory minimum should be alleged in an indictment and found by a jury beyond a reasonable doubt.

5. The Defendant understands that the obligations of the Government within the Plea Agreement are expressly contingent upon the Defendant's abiding by federal and state laws.

6. In the event that the Defendant fails to comply with any of the provisions of this Agreement, either expressed or implied, it is understood that the Government will have the right, at its sole election, to void all of its obligations under this Agreement and the Defendant will not have any right to withdraw its plea of guilty to the offense enumerated herein.

Cooperation and Forfeiture

7. The Defendant agrees to be fully truthful and forthright with federal, state and local law enforcement agencies by providing full, complete and truthful information about all criminal activities about which it has knowledge. The Defendant must provide full, complete and truthful debriefings about these unlawful activities and must fully disclose and provide truthful information to the Government including any books, papers, or documents or any other items of evidentiary value to the investigation. The Defendant through its duly authorized agents must also testify fully and truthfully before any grand juries and at any trials or other proceedings if called upon to do so by the

Government, subject to prosecution for perjury for not testifying truthfully. The failure of the Defendant to be fully truthful and forthright at any stage will, at the sole election of the Government, cause the obligations of the Government within this Agreement to become null and void. Further, it is expressly agreed that if the obligations of the Government within this Agreement become null and void due to the lack of truthfulness on the part of any duly authorized agent of the Defendant, the Defendant understands that:

- (A) the Defendant will not be permitted to withdraw its plea of guilty to the offenses described above;
- (B) all additional charges known to the Government may be filed in the appropriate district;
- (C) the Government will argue for a maximum sentence for the offense to which the Defendant has pleaded guilty; and
- (D) the Government will use any and all information and testimony provided by the Defendant in the prosecution of the Defendant of all charges.

8. The Government agrees that any self-incriminating information provided by the Defendant as a result of the cooperation required by the terms of this Agreement, although available to the Court, will not be used against the Defendant in determining the Defendant's applicable guideline range for sentencing pursuant to the U.S. Sentencing Commission Guidelines. The provisions of this paragraph shall not be applied to restrict any such information:

- (A) known to the Government prior to the date of this Agreement;
- (B) concerning the existence of prior convictions and sentences;
- (C) in a prosecution for perjury or giving a false statement; or
- (D) in the event the Defendant breaches any of the terms of the Plea Agreement.

9. The Defendant consents to the entry of a personal money judgment against the Defendant and in favor of the United States in the amount of ten million dollars (\$10,000,000) in United States currency, as of the date of entry of judgment. The full amount of the money judgment is payable on or before the date of sentencing.

The Defendant agrees to forfeit all interests in and not to contest the \$10,000,000 forfeiture by the United States of America. The Defendant further agrees to prevent the disbursement, relocation or encumbrance of this money and agrees to fully assist the government in the recovery and return to the United States of the money, or portions thereof, as described above, wherever located. The Defendant further agrees to make a full and complete disclosure of all assets over which Defendant exercises control and those which are held or controlled by nominees. The Defendant further agrees to submit appropriate documentation, sworn to under penalty of perjury, on the issue of assets if it is deemed necessary by the United States.

Should it become necessary to collect on the money judgment, the Defendant agrees to take whatever steps are necessary to convey to the United States of America title to other assets and property up to the value of the unpaid judgment. These steps

include, but are not limited to, the surrender of title and the signing of any other documents necessary to effectuate such transfers. The Defendant agrees not to object to any civil proceedings brought against any assets or properties pursuant to any provision of law and the Defendant further understands that any such civil proceedings may properly be brought if the agreed-upon payment is not timely made. Defendant also agrees to waive any double jeopardy claims it may have as a result of the forfeiture of such assets or properties as provided for by this Agreement.

No Further Prosecution; Government's Recommendation Regarding Sentencing

10. Pursuant to Federal Rule of Criminal Procedure 11(c)(1)(A), the Government agrees that, other than the charge in the Information, it shall not further prosecute Leiner Health Products LLC or any corporate parent, subsidiary, or affiliate thereof for conduct which (a) falls within the scope of the Information or (b) was known to the U.S. Attorney's Office prior to the date of execution of this Agreement. The parties agree that the U.S. Attorney's Office is aware of the allegations in the FDA Form 483 dated March 16, 2007, the FDA Warning Letter dated August 28, 2007, and the affidavit in support of the search warrant executed on September 5, 2007. The parties agree that the number of lots identified in the Information is a reasonable approximation of the extent of the affected lots, and the Government will not further prosecute Leiner for other lots with respect to the allegations in the FDA Form 483, the FDA Warning Letter, and the search warrant affidavit concerning the production, testing, and distribution of OTC products at the Ft. Mill facility. The U.S. Attorney's Office is not aware of any

allegations of adverse health effects relating to the matters alleged in the FDA Form 483, the FDA Warning Letter, and the search warrant affidavit, and the Government's non-prosecution obligation shall not apply to any such allegations in the event such allegations should arise in the future. The Government's non-prosecution obligation in this paragraph is expressly contingent on: (1) the guilty plea of Leiner Health Products LLC being accepted by the Court and not withdrawn; and (2) Leiner Health Products LLC's performance of all of its material obligations as set forth in this Agreement. The Government expressly reserves the right to prosecute any individual in connection with the conduct encompassed by this Agreement.

11. Pursuant to Federal Rule of Criminal Procedure 11(c)(1)(B), the Government agrees that it will recommend to the Court that (a) the Defendant be sentenced to pay the sum of ten million dollars (\$10,000,000) as a forfeiture in lieu of a fine; and (b) that the Defendant be required to pay a special assessment of \$400.

Corporate Authorization

12. The Defendant's acknowledgment of this Agreement and execution of this Agreement is evidenced by the signature of its corporate officer below. The Defendant shall provide to the Government and to the Court a resolution of the Board of Directors of Leiner, affirming that the Board of Directors has authority to enter into this Agreement and has (1) reviewed the Information in this case and this Agreement or has been advised of the contents thereof; (2) consulted with the Defendant's legal counsel in connection with the matter; (3) voted to enter into the proposed Plea Agreement; (4)

voted to authorize Leiner to plead guilty to the charge specified in the Information; and (5) voted to authorize the corporate officer identified below to execute the Plea Agreement and all other documents necessary to carry out the provisions of the Plea Agreement.

Merger and Other Provisions

13. The Defendant represents to the Court that it has met with its attorneys on a sufficient number of occasions and for a sufficient period of time to discuss the Defendant's case and receive advice; that the Defendant has provided truthful information to its attorney and related all information of which the Defendant is aware pertaining to the case; that the Defendant and its attorney have discussed possible defenses, if any, to the charges in the Information, including the existence of any exculpatory or favorable evidence or witness, discussed the Defendant's right to a public trial by jury or by the Court, the right to the assistance of counsel throughout the proceedings, the right to confront and cross-examine the government's witnesses, the Defendant's right to provide testimony on its own behalf, or to remain silent and have no adverse inferences drawn from his silence; and that the Defendant, with the advice of counsel, has weighed the relative benefits of a trial by jury or by the Court versus a plea of guilty pursuant to its Agreement, and has entered this Agreement as a matter of the Defendant's free and voluntary choice, and not as a result of pressure or intimidation by any person.

14. The Defendant is aware that 18 U.S.C. § 3742 and 28 U.S.C. § 2255 afford every

defendant certain rights to contest a conviction and/or sentence. Acknowledging those rights, the Defendant, in exchange for the concessions made by the Government in this Plea Agreement, waives the right to contest either the conviction or the sentence in any direct appeal or other post-conviction action, including any proceedings under 28 U.S.C. § 2255. This waiver does not apply to claims of ineffective assistance of counsel or prosecutorial misconduct. This Agreement does not affect the rights or obligations of the Government as set forth in 18 U.S.C. § 3742(b). Nor does it limit the Government in its comments in or responses to any post-sentencing matters.

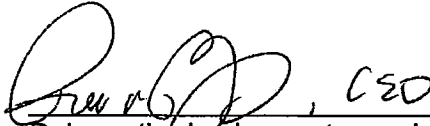
15. The Defendant waives all rights, whether asserted directly or by a representative, to request or receive from any department or agency of the United States any records pertaining to the investigation or prosecution of this case, including without limitation any records that may be sought under the Freedom of Information Act, 5 U.S.C. § 552, or the Privacy Act of 1974, 5 U.S.C. § 552a.

16. This plea agreement is binding upon Leiner, its corporate parent, affiliates, and subsidiaries, including LHP Holding Corp. and Leiner Health Products.

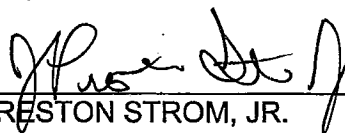
17. The parties hereby agree that this Plea Agreement contains the entire agreement of the parties; that this Agreement supersedes all prior promises, representations and statements of the parties; that this Agreement shall not be binding on any party until the Defendant tenders a plea of guilty to the Court having jurisdiction over this matter; that this Agreement may be modified only in writing signed by all parties; and that any and all other promises, representations and statements, whether made prior to,

contemporaneous with or after this Agreement, are null and void.

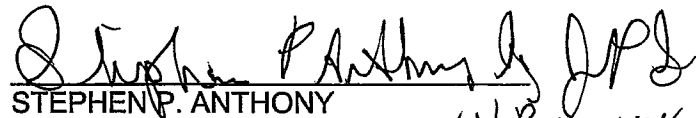
June 11, 2008
DATE

, CEO
Duly authorized agent, on behalf of
LEINER HEALTH PRODUCTS, LLC,
Defendant

June 11, 2008
DATE

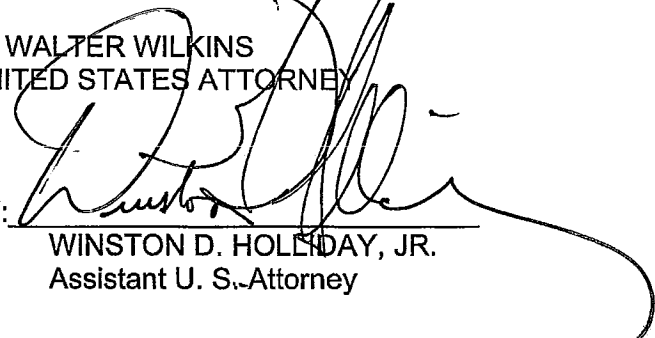

J. PRESTON STROM, JR.
Attorney for the Defendant

June 11, 2008
DATE


STEPHEN P. ANTHONY
Attorney for the Defendant *w/ permission*

W. WALTER WILKINS
UNITED STATES ATTORNEY

June 11, 2008
DATE

BY: 
WINSTON D. HOLLIDAY, JR.
Assistant U. S. Attorney